National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

DCT Adverse Reaction Form for Investigational Agents

ADR # *Assigned at NCI*

Please Print or Type

Person completing the form: _____

Phone No.: _____ **Date:** _____

Physician responsible for this report: _____

I. DEMOGRAPHICS

A. Patient Information

Pt. ID: _____ Age: _____ Sex: _____ Date of initial Dx: _____

Malignancy: _____

Site of primary: _____ PS (at start of study): _____

Site(s) of Metastatic disease: _____

Concurrent non-malignant disease and non-protocol medications: _____

B. Agent Information:

Agent name: _____

Source of agent: ☐ NCI ☐ Other/specify _____

Type of reaction: _____ Toxicity grade: _____

Date of reaction: _____ Date IRB notified: _____

NCI Protocol No.: _____ Attending Physician (Investigator): _____

Phase of study: _____ Institution: _____ Phone No.: _____

Protocol treatment (include all agents):

Agent	Dose	Schedule	Route

Date first course started: _____ Number of courses: _____

Date last course started: _____ Date of therapy associated with ADR: _____

Prior therapy (agent, radiation, relevant surgery/include dates of therapy): _____

II. DOCUMENTATION OF REACTION

A. Non-myelosuppressive toxicity and previously unknown Myelosuppression

1. Description of reaction and temporal relationship to investigational agent administration:

2. Physical findings and laboratory data (e.g. bilirubin, creatinine, including baseline, worst, and recovery value) documenting toxicity:

3. Treatment of adverse reaction:

4. Past history of organ dysfunction:

5. Re-challenge with agent: ☐ yes ☐ no

If yes: _____ With reaction; describe _____

_____ Without reaction

6. Patient outcome: _____ Recovered without sequelae

_____ Recovered with sequelae; describe _____

_____ Remains under treatment

_____ Died/from ☐ ADR ☐ Malignancy ☐ Other _____

Autopsy date: _____

B. Myelosuppression (previously known or unknown)

1. Laboratory data documenting Myelosuppression

	Baseline: Date/Value	Nadir: Date/Value	Recovery or Latest Value: Date/Value
WBC or PMN:	/	/	/
Platelets:	/	/	/
HGB or HCT:	/	/	/

2. Complications, treatment and sequelae (e.g. infections/hemorrhage)

C. Grade of toxicity and reporting requirements (Check one)

1. Previously unknown toxicities:

a) Fatal ☐ or Life-Threatening ☐ (Report by telephone within 24 hours: (301) 230-2330)

Date: _____ NCI Contact: _____

b) Grade: I ☐ II ☐ III ☐ (Send form within 10 days)

2. Previously known Non-Myelosuppressive toxicities:

a) Fatal ☐ or Life-Threatening ☐ (Send form within 10 days)

3. Previously known Myelosuppressive toxicities:

a) Fatal ☐ (Send form within 10 days)

Send forms to: Investigational Drug Branch, NCI
Post Office Box 30012
Bethesda, MD 20824

D. Investigator's Assessment (If more than 1 investigational agent was used, give an assessment for each by writing the agent names on the appropriate lines):

	IND Agent	Non-IND	Disease
Unrelated	☐	☐	☐
Unlikely	☐	☐	☐
Possible	☐	☐	☐
Probable	☐	☐	☐
Definite	☐	☐	☐

Action Taken:
- ☐ None
- ☐ Dose reduced
- ☐ Dose withheld
- ☐ Agent discontinued

Therapy Required:
- ☐ None
- ☐ Symptomatic
- ☐ Supportive
- ☐ Intensive

E. I hereby certify that the information on this form is correct and complete to the best of my knowledge.

_____ **M.D.** _____

Signature of Responsible Physician ***Date***